UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/147,955	03/24/1999	MASAKO MIZUTANI	001560-350	2480

21839 7590 07/03/2002

BURNS DOANE SWECKER & MATHIS L L P
POST OFFICE BOX 1404
ALEXANDRIA, VA 22313-1404

EXAMINER	
IBRAHIM, MEDINA AHMED	
ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 07/03/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/147,955	MIZUTANI ET AL.	
	Examiner	Art Unit	
	Medina Ibrahim	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 April 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-11 and 16-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-11,16-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-7, 9-11, 16-19, and 20-24 are pending and are under examination.

The response filed 04/03/02 and the supplemental response with attachment of 4/15/02 have been considered.

Withdrawn rejections and Objections

The objection to the specification, the rejection under 35 U.S.C. 112, 2nd paragraph to claims 3-4, 22 and 24 regarding "homology", to claim 5 regarding "can be hybridized", to claim 10-11 and 16-19 regarding "identical properties", to claims 19, 20, 22-23, and 24 have been withdrawn in view of Applicant's amendment to the claims in the response filed 4/03/02. The rejections to claims 1, 6-7, 9-11 and 20-21 under 35 USC, 112, 1st paragraph regarding scope and written description have been withdrawn upon further consideration.

Claim Rejections - 35 USC 112, 2nd paragraph

Claims 2-5, 16-19 and 22 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 2-5 recite " amino acid sequence of SEQ ID NO:1, 3, 5, 7, or 9. As indicated in the last Office action, SEQ ID NO:1, 3, 5, 7, or 9 are nucleotide sequences, not amino acid sequences. Claim 22 recites "a nucleotide sequence as set forth in SEQ ID NO:7-10 or 12. However, SEQ ID NO: 8, 10, and 12 are not nucleotide sequences, as pointed out in the last Office action. Dependent claims 16-19 remain rejected.

Claim 9 remain rejected in the recitation of "breeding" for the same reason stated in the last Office action. Applicants' assertion that "breeding" is a term of art used for plant cells, similar to the use of "culturing" for microorganisms is incorrect because while breeding is a term art used for plant cells, it is not commonly used for the production of protein in plant/plant cells. Applicants' specification does not define "breeding" and one skilled in the art would not understand the term as used in the claim. In addition, the terms "breeding" and "culturing" are not interchangeably used in the art. Therefore, the rejection is maintained.

In claim 5, "said gene" lacks antecedence basis.

35 USC 112, 1st paragraph, Scope of Enablement

Claims 2-7, 9-11, 16-19 and 22-24 remain rejected and ~~new claim 30~~ MAI is rejected under 35 U.S.C. 112, first paragraph, because the specification while being enabling for an isolated DNA coding for a protein having 5GT activity, including the protein of SEQ ID NO:2, 4, 6, or 8, vector containing said DNA, a plant into which said DNA is introduced, its progeny or tissue that retains said DNA, and a process for producing and recovering a protein having 5GT activity from a host cell, does not provide enablement for any DNA coding for a modified protein having additions and/or deletions and/or substitutions of one or more amino acids, or for a protein having amino acid sequence identity of 30% or 50 % or more to the disclosed sequence that retains 5GT activity, or a DNA that hybridizes under the specified hybridization conditions with all or portion of one of the disclosed nucleotide sequence or a partially complementary sequence thereof and still encoding for a protein having 5GT activity, or a plant or a plant cell transformed with said DNA. This rejection is repeated for the same reasons of record as set forth in the Office action

mailed on 10/03/01. Applicants' arguments filed on 4/03 and 4/15 of 2002 have been fully considered but they are not persuasive.

Contrary to Applicant's arguments in pages 9-10 of the response, claims broadly drawn to a DNA coding for a protein modified by additions and/or deletions and/or substitutions of one or more amino acids relative to one of the disclosed sequences, or a protein having an amino acid sequence identity of 30% or 50% or more to the disclosed amino acid sequences and still retaining 5GT activity, or a DNA that is partially complementary or hybridizes to SEQ ID NO:1, 3, 5, 7, or 11 under the hybridization conditions of claims 5 and 23 and still encoding for a protein having 5GT activity are not supported by an enabling disclosure for the reasons disclosed in previous Office actions. The instant specification does not disclose or provide guidance for how to identify and isolate all of the claimed DNAs. No guidance has been presented for any modifications to the disclosed DNA/protein sequences that resulted the DNA/protein of claims 2-5. The specification provided no guidance as to which region in the disclosed protein can be modified so that 5GT protein activity is retained.

In response to Applicants argument that it is well known in the art that an enzyme molecule comprises regions involving enzyme activity and regions not essential for enzymatic activity, so modifications in the nonessential region may maintain the activity, it is note that no regions essential or nonessential for the 5GT activity have been disclosed in the instant application and it is unclear if these regions are well known in the art. Absent any guidance as to which region in SEQ ID NO:2, 4, 6, 8, or 12 can be modified by additions and/or deletions and/or substitutions

so as the protein activity is maintained, one skilled in the art would not be able to make and use the claimed DNA without undue experimentations.

Regarding claims drawn to a DNA encoding a protein having 35% or 50% or more sequence identity to one of the disclosed sequence, it is maintained that the specification is not enabling for all DNAs encoding a protein having 30% or 50% more sequence identity to one of the disclosed sequence. For example Bandurske et al (disclosed in page 4 of the Office action of 10/03/01) teach a plant gene encoding a non- 5GT protein that has 30% and 35% overall and local similarity, respectively, to Applicant's SEQ ID NO:12. Applicants have not specifically addressed this rejection and is believed to be in order. Applicants should note that no working examples have been disclosed for any modified DNA/protein sequence or having less than 100% sequence identity to one of the disclosed DNA/protein that retains 5GT activity.

Regarding the hybridization conditions of claims 5 and 23-24, neither the instant specification nor Applicants' response provides evidence that all DNA obtainable under the claimed mild hybridization conditions would provide a functional protein having 5GT activity. Therefore, one skilled in the art would not be able to practice the instant invention as broadly claimed without undue trial and error experimentation, as stated in the Office action.

The reference by Jeffrey B. Harborne submitted with the amendment of 4/15/02 is not persuasive with respect to instantly rejected claims.

35 USC 112, 1st paragraph, Written Desription

Claims 1, 6-7, 9-11, and 20-21 remain rejected under 35 U.S.C. 112, first paragraph, as the specification does not provide adequate written desription of the invention as broadly claimed.

This rejection is repeated for the same reasons of record as set forth in the Office action mailed on 10/03/01. Applicants' arguments filed on 4/03 and 4/15 of 2002 have been fully considered but they are not persuasive.

Applicant's arguments in pages 11-13 of the response that given the description of the genus of the 5GT gene and the significant degree of homology in the proteins between different plant species as well as the information provided in the specification regarding how to identify additional 5GT genes, one skilled in the art would recognize that the inventors had possession of the invention as claimed are not persuasive for the reasons set forth in pages 6-7 of the action mailed 10/03/01.

Regarding the *Eli Lilly* case law, the Office maintains that this situation is analogous where it says " to adequately describe a claimed genus, Applicant must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to "visualize or recognize the identity of members of the genus". Id. In the instant case, Applicants have disclosed genes from *Perilla frutescens, Verbena, Petunia and Torenia hybrida*. However, it is unclear if few genes from four plant species are a representative sample of genus, namely, any 5GT from any source, even the disclosed genes share high protein homology. Accordingly, the claimed invention lacks adequate written description. Regarding the arguments that the specification describes how to obtain 5GT from four different plant species and that the other 5GT genes can be obtained by using a portion or the entirety of a 5GT gene, Applicants should note that this is not an enablement rejection. The requirements for a "written description" and "an

enabling disclosure" are separate. The separateness of the two requirements has been emphasized in *Fiers v. Sugano* [25 USPQ2d 1601(Fed. Cir. 1993)].

Therefore, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

Claims 20-23 remains rejected under 35 U.S.C. 102(b) as being anticipated by Brugliera et al (US 5, 859, 334 filed March 1995. This rejection is repeated for the same reasons of record as set forth in page 9 of the Office action mailed on 10/03/01. Applicants arguments filed on 4/03/02 have been fully considered but they are not persuasive.

Contrary Applicant's argument in page 15 of the response, the claimed DNA that is complementary to a sequence encoding a plant flavonoid 5GT does not require to encode a protein having 5GT activity. The claims are drawn to a sequence complementary to a nucleotide sequence encoding a plant flavonoid-5GT, or the complementary sequence of SEQ ID NO:1, 3, 5, 7, or 11. Applicants should note that since SEQ ID NO:1, 3, 5, 7, or 11 is the encoding strand, the complementary strand thereof cannot encode a protein.

Applicants should also note that a "complementary" which is not defined in the specification is open to a wide variety of interpretations. In this case, it is defined as a 2-mer sequence.

To obviate this rejection, it is suggested that a "complementary" be replaced with a ---fully complementary--.

Claim Rejections - 35 USC § 103

Claims 1-7, 9-11, 16-19, and 20-24 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Brugliera et al (US 5, 859, 334) in view of Jonsson et al and Sambrook et al.. This rejection is repeated for the same reasons of record as set forth in page 9 of the Office action mailed on 10/03/01. Applicants arguments filed on 4/03/02 have been fully considered but they are not persuasive.

Applicants maintain the arguments that combination of the cited references fails to disclose or even suggest the claimed invention. Applicants have relied upon the following points to support their position:

-all claims require that the DNA be coding for a protein having 5GT activity.

-Brugliera et al teaches only 3RT protein which has only 23% and 26% of sequence identity to Applicants' 5GT.

-the sole reference to 5GT in Brugliera et al is the statement that "the invention is directed to an isolated nucleic acid molecule comprising a sequence of nucleotides encoding or complementary to a sequence encoding a plant glycosyltransferase selected from the group consisting of 3RT and 5GT". The mere mention of the 5GT protein is hardly an enabling disclosure suggesting the claimed isolated DNA.

-Jonsson et al describes a partially purified anthocyanin 5GT, but not a purified enzyme or even partial amino acid sequence.

-Sambrook et al does not teach anything regarding the DNA encoding a 5GT protein.

Applicants arguments are not persuasive for the reasons of record.

As stated in the last Office action, none of the cited references need to teach a DNA encoding a protein having 5GT as recited in the claimed invention, since the rejection is one of obviousness. Brugliera et al reasonably suggest a DNA encoding a protein having 5GT and provides the reasonable expectation of success for the use of a glycosyltransferase gene for the production of GT enzymes in a plant-based expression system.

-Jonsson et al need not teach the purified or the amino acid sequence of 5GT protein because one skilled in the art can easily obtain purified or sequenced 5GT protein using methods available in the prior art, such as Sambrooke et al, or by just following the procedure disclosed by Brugliera et al for the cloning, isolating and sequencing of 3RT gene/protein.

While the combination of Bruglier et al, Jonsson and Sambrook does not teach or suggest Applicants' SEQ ID NO:1, 3, 5, 7, or 11 encoding SEQ ID NO:2, 4, 6, 8, or 12, the variants encompassing DNA encoding a protein having as low as 30% or 50% sequence identity, or that hybridizes under mild to low hybridization conditions to the disclosed sequences are obvious over the cited references, absent clear and convincing evidence to the contrary. Claims 1, 6-7, 9-11 are included in the rejection because no features that distinguish the claimed "5GT" DNA/protein from the 5GT of the prior art were presented. In addition, Applicants' statements (to overcome scope of enablement rejection) in page 9, 2nd full paragraph, and the paragraph bridging pages 9 and 10 of the response support the rejection to claims drawn to "any full length 5GT DNA/protein".

See also *In re Lindner*, 173 USPQ 356 (CCPA 1972) and *In re Grasselli*, 218 USPQ 769 (Fed. Cir. 1983), disclosed in the last Office action which teaches that the evidence of unexpected

results should be commensurate with the scope of the claims. In this case, Applicants' unexpected result, namely, the isolated DNA of SEQ ID NO:1, 3, 5, 7, 9, or 11 or a DNA encoding SEQ ID NO:2, 4, 6, 8, 10, or 12 is not commensurate with undisclosed variants thereof.

Remarks

No claim is allowed.

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The

Examiner can normally be reached Monday -Tuesday from 8:00 AM to 5:00 PM and Wednesday-Thursday from 9:00AM to 3:00PM

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

June 22, 2002
mai

PHUONG T. BUI
PRIMARY EXAMINER 7/1/02